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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,229	03/27/2001	Alastair V. Ferguson	1669.0040001/SRL/BLS	8063

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/27/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,229

Applicant(s)

FERGUSON ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 1 and 4 have been amended and claims 21 and 22 have been cancelled as requested in the amendment of Paper No. 9, filed on June 11, 2002. Claims 1-20 are pending in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on June 11, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. Claims 1-20 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in section 4 of Paper No. 8.

Applicant traverses the rejection on the premises, in part, that "[I]t would not require undue experimentation for a skilled artisan to use the disclosed method in any type of cell expressing a transient K⁺ conductance" (page 5, last paragraph of the Response). Applicant refers to Rogawski publication, which demonstrates that the membranes of most excitable cells

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contains a set of potassium channels, as well as to additional data, which shows that the claimed method "will also work in neurons of the nucleus tractus solitarius of the brain" (page 6, first paragraph). This has not been found to be persuasive for the following reasons.

Claims 1-20 are directed to a method of preventing damage to the excitable cells of a patient that express a transient potassium conductance by means of administration of a compound, which increases potassium current in the excitable cells of a patient. The claimed invention is supported by working examples, which are limited to histological study and electrophysiological recording of brain slices of hypothalamic area after intracranial injection of different factors, including saralasin. The state of the art is such that there is no information disclosed for a skilled artisan to rely upon in an attempt to extrapolate the limited results presented in the instant specification to practice the claimed method with a reasonable expectation of success. To practice such method of preventing the damage to the excitable cells, even assuming that all such cells possess a transient potassium channel, would require undue experimentation on part of a routine practitioner. The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that systemic administration of a compound, which has been shown to increase transient potassium current *in vitro* on brain slices, would have a single similar effect and, for example, no other effects. Claim 10, for instance, is directed to a compound that is a vasopressin receptor antagonist. One of ordinary skill in the art readily recognizes that administration of a vasopressin receptor antagonist will lead to a plurality of effects, one of which might be an increase of a transient potassium current in the excitable cells; however, there is no basis of concluding that such administration will lead to preventing damage to the excitable cells of a patient.

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Applicant refers to *In re Moore* to support the claims that encompass all known and unknown compounds that increase transient potassium current. This is not persuasive because claims 1-19 are single means claims in that they recite "a compound which increases a transient potassium (K^+) current in the excitable cells". MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (such as increasing a transient K^+ current in the excitable cells), a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification.

Applicant's response to the quoted case (*In re Colianni*), see page 10, second paragraph of the Response, is not persuasive for the reasons explained earlier. Briefly, the absence of guidance in the instant specification regarding the amount and duration of administration of compound which increases potassium current in the excitable cells and a suitable route of such administration would lead to undue experimentation on part of a routine practitioner, who would have to resort to a substantial amount of undue experimentation. The Examiner strongly disagrees with Applicant's position that "one of ordinary skill in the art would easily determine such parameters". On the contrary, the amount of experimentation seems to be significant and undue.

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Information Disclosure Statement

5. It is understood that Applicant has submitted copies of Documents AC1 and AR2 of the IDS first time with the Paper No. 5 and the second time with the amendment of Paper No. 9. However, unfortunately, these copies were never received. The Examiner regrets this incident; however, in order for the papers to be considered the copies have to be present in the file.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

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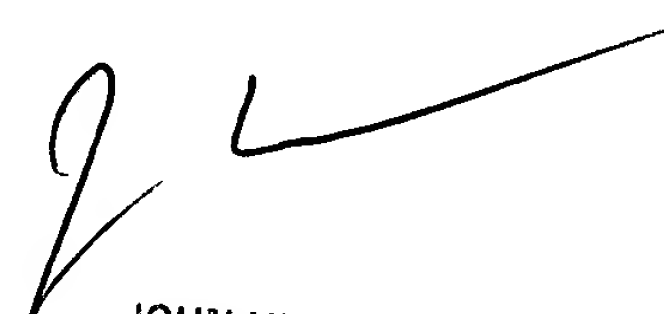
signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
August 23, 2002

OC


JOHN ULM
PRIMARY EXAMINER
GROUP 1800